REMARKS

Claims 7-9 were pending. Claim 9 is allowed. In the instant amendment, claims 7 and 8 have been amended. Claims 10 and 11 have been added. Upon entry of the present amendment claims 7-11 will be pending and under consideration.

I. AMENDMENT TO THE CLAIMS

Support for the amendments to claims 7 and 8 is found, for example, on pages 1, 2, and 10 of the specification and claims 2 and 4 as originally filed.

Support for new claims 10 and 11 is found, for example, on page 5, lines 16-32, and page 9, line 3, to page 11, line 6.

The amendments do not introduce new matter and they are fully supported by the instant specification and the claims as originally filed. Entry of the amendments is respectfully requested.

II. REJECTION UNDER 35 U.S.C. § 101

Claim 7 stands rejected under 35 U.S.C. § 101, as allegedly being directed to non-statutory subject matter for reading upon a product of nature. This rejection is overcome in view of the amendment to claim 7 reciting in pertinent part "an *isolated* hereditary hemochromatosis (HFE) polypeptide." Applicants respectfully request that the rejection of claim 7 under 35 U.S.C. § 101 be withdrawn.

III. REJECTION UNDER 35 U.S.C. § 102(e)

Claims 7 and 8 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by either U.S. Patent No. 6,025,130 to Thomas *et al.* ("the '130 patent") or U.S. Patent No. 6,140,305 to Thomas *et al.* ("the '305 patent"). Applicants respectfully traverse.

In order for a reference to anticipate under 35 U.S.C. § 102, the standard is strict identity. *See Structural Rubber Prod. Co. v. Park Rubber Co.*, 749 F.2d 707, 715, 223 U.S.P.Q. 1264 (Fed. Cir. 1984); M.P.E.P. § 2131. Anticipation can be established only by a single reference that teaches each and every element of the claimed invention; anticipation is not shown even if the differences between the claims and the cited reference are argued to be "insubstantial" and the missing elements could be supplied by the knowledge of one skilled

in the art. *Structural Rubber,* 749 F.2d at 716. Furthermore, in *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 756 F.2d 1556, 1560, 225 U.S.P.Q. 253 (Fed. Cir. 1985), the court pointed out that the assertion of invalidity for lack of novelty is erroneous if a reference teaches "substantially the same thing." A cited reference must meet each claim limitation in order to constitute anticipation.

In this case, amended claims 7 and 8 recite in pertinent part "a . . . polypeptide *consisting* of the amino acid sequence of" SEQ ID NO:1 or SEQ ID NO:2, respectively. Applicants respectfully submit that neither the '130 patent nor the '305 patent teach a composition comprising an isolated HFE polypeptide consisting of the amino acid sequences of SEQ ID NO:1 or 2 and a human β_2m. Accordingly, Applicants respectfully request that the rejection of claims 7 and 8 under 35 U.S.C. § 102(e) be withdrawn.

IV. NEW CLAIMS 10 and 11

New claims 10 and 11 are directed towards compositions comprising isolated HFE polypeptides of SEQ ID NO: 1 and SEQ ID NO: 2, respectively, and a full length, wild-type human β_2m suitable for administration to a subject. Applicants respectfully submit that neither the '130 patent nor the '305 patent teach the recited combination in a composition suitable for administration to a subject.

CONCLUSION

Applicants submit that Claims 7-11 meet the conditions for patentability and are in condition for allowance.

No fees, other than those for an extension of time and for the claim amendment, are believed due with this response, however, the Commissioner is authorized to charge any

underpayment or credit any overpayment to Deposit Account No. 16-1150 (order no. 8907-098-999) for any matter in connection with this response which may be required.

Respectfully submitted,

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54,398
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